Pyxis Oncology Provides Business Update and Reports Third Quarter 2025 Financial Results

November 3, 2025

- Preliminary data from ongoing Phase 1 clinical studies of micvotabart pelidotin (MICVO) in patients with recurrent and metastatic head and neck squamous cell carcinoma (R/M HNSCC) expected in the fourth quarter of 2025

- Clinical update to focus on preliminary data from Phase 1 monotherapy dose expansion study of MICVO in 2L/3L R/M HNSCC patients, including from both post platinum & PD-1 and post EGFR & PD-1 arms, and preliminary data from Phase 1/2 combination dose escalation study of MICVO and KEYTRUDA® (pembrolizumab) in 1L/2L+ R/M HNSCC patients

- Presented translational data at ESMO 2025 and AACR-NCI-EORTC providing meaningful insights into MICVO's first-in-concept non-cellular targeting antibody drug conjugate (ADC) mechanism of action

- Expected cash runway through data milestones and into the second half of 2026

BOSTON, Nov. 03, 2025 (GLOBE NEWSWIRE) -- Pyxis Oncology, Inc. (Nasdaq: PYXS), a clinical-stage company developing next-generation therapeutics for difficult-to-treat cancers, today provided a business update, and reported financial results for the quarter ended September 30, 2025.

"In the dynamic landscape of emerging clinical-stage therapies for patients with recurrent and metastatic head and neck squamous cell carcinoma, a significant unmet medical need remains despite the potential improvements in treatment options," said Lara S. Sullivan, M.D., President, Chief Executive Officer and Chief Medical Officer of Pyxis Oncology. "We look forward to presenting our preliminary data from the ongoing clinical studies evaluating MICVO as a novel potential treatment option for recurrent and metastatic head and neck squamous cell carcinoma. We believe that the breadth of the MICVO clinical program, encompassing monotherapy and combination approaches, holds significant promise and this inflection point will further underscore our first-in-concept ADC's potential to improve outcomes across multiple lines of therapy."

Pipeline & Corporate Updates

- Pyxis Oncology expects to report preliminary data from the ongoing Phase 1 clinical studies of micvotabart pelidotin (MICVO) in patients with recurrent and metastatic head and neck squamous cell carcinoma (R/M HNSCC) in 4Q25.
    - Clinical update to focus on preliminary data from the Phase 1 monotherapy dose expansion study of MICVO for 2L/3L R/M HNSCC patients, including both the post platinum and anti-PD(L)-1 experienced arm and the post EGFRi and anti-PD(L)-1 experienced arm.
    - Additional preliminary clinical data from the Phase 1/2 combination dose escalation study of MICVO and KEYTRUDA® (pembrolizumab) for 1L/2L+ R/M HNSCC patients will also be provided. The combination study is part of a Clinical Trial Collaboration Agreement with Merck (known as MSD outside of the US and Canada).
    - Pyxis Oncology expects to announce next steps in the clinical development plan for MICVO for R/M HNSCC along with the preliminary data update.
- Pyxis Oncology presented new translational data in October 2025 in two posters at the *European Society for Medical Oncology (ESMO) Congress 2025* and in six posters at the *AACR-NCI-EORTC International Conference*, as well as three clinical trial in progress posters at *ESMO*. The presentation posters at *ESMO* and *AACR-NCI-EORTC* provided deeper insights into the pharmacodynamic responses of tumors to MICVO as well as MICVO's unique mechanism of action and its potential to exert anti-tumor activity through three mechanisms: direct tumor cell killing, bystander killing and immunogenic cell death.
    - Translational findings highlighted MICVO's effects on tumor microenvironment remodeling and immune activation, further reinforcing the potential benefit of MICVO as both a monotherapy and in combination with anti-PD1 therapy.
    - Observations included changes in circulating tumor DNA (ctDNA) tumor fraction (TF) to the vast majority of 37 clinical samples tested. Notably, reduction in ctDNA TF after treatment with MICVO, particularly in HNSCC and at the 5.4 mg/kg dose, support a positive molecular response to MICVO and strengthen rationale for continued development for this tumor type and dose in the monotherapy dose expansion study.
    - Additionally, features observed in nonclinical samples of the stromal architecture detected using AI-enabled hyper-resolution digital pathology may correlate with sensitivity to MICVO - a finding that may be unique compared to tumor cell surface targeting ADCs, due to MICVO's targeting of a non-cellular structural component of the extracellular matrix.

Third Quarter 2025 Financial Results

- As of September 30, 2025, Pyxis Oncology had cash and cash equivalents, including restricted cash, and short-term investments, of $77.7 million. The Company believes that its current cash, cash equivalents, and short-term investments will be sufficient to fund its operations into the second half of 2026.

- Research and development expenses were $17.8 million for the quarter ended September 30, 2025, compared to $17.7 million for the quarter ended September 30, 2024. MICVO program-specific research and development costs increased by $2.0 million, primarily due to a $1.0 million increase in contract manufacturing costs and a $1.3 million increase in clinical trial related expenses related to monotherapy and combination therapy of MICVO. The increase in expenses was partially offset by a $1.8 million reduction in expenses related to PYX-106, as the clinical development of PYX-106 was paused in December 2024.

- General and administrative expenses were $5.6 million for the quarter ended September 30, 2025, compared to $6.0 million for the quarter ended September 30, 2024. The decrease was primarily due to lower corporate insurance costs and a decrease in legal, professional and consulting fees.

- Net loss was $22.0 million, or ($0.35) per common share, for the quarter ended September 30, 2025, compared to $21.2 million, or ($0.35) per common share, for the quarter ended September 30, 2024. Excluding non-cash stock-based compensation expense, the net loss for the quarter ended September 30, 2025 was $18.9 million, compared to a net loss of $18.2 million for the quarter ended September 30, 2024.

- As of October 31, 2025, the outstanding number of shares of Common Stock of Pyxis Oncology was 62,264,215.

About Pyxis Oncology, Inc.
Pyxis Oncology, Inc. is a clinical stage biopharmaceutical company developing therapeutics for difficult-to-treat cancers. The Company's lead candidate, micvotabart pelidotin (MICVO), is a first-in-concept antibody drug conjugate (ADC) that targets extradomain-B of fibronectin (EDB+FN), a non-cellular structural component of the tumor extracellular matrix (ECM). EDB+FN is selectively overexpressed in the tumor microenvironment of a wide range of solid tumors and largely absent from normal adult tissues. MICVO is designed to treat solid tumors through a three-pronged mechanism of action: direct tumor cell killing, bystander effect and immunogenic cell death. MICVO is currently being evaluated in Phase 1 clinical studies in patients with recurrent and metastatic head and neck squamous cell carcinoma (R/M HNSCC) and other solid tumors, both as monotherapy and in combination with Merck's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab). Pyxis Oncology is focused on advancing MICVO, with the goal of improving outcomes for patients living with R/M HNSCC and contributing to meaningful progress in cancer treatment.

MICVO received Fast Track Designation from the U.S. Food and Drug Administration for the treatment of adult patients with R/M HNSCC whose disease has progressed following treatment with platinum-based chemotherapy and an anti-PD-(L)1 therapy.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

To learn more, visit www.pyxisoncology.com or follow us on LinkedIn.

Forward Looking Statements
This press release contains forward-looking statements for the purposes of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995 and other federal securities laws. These statements are often identified by the use of words such as "anticipate," "believe," "can," "continue," "could," "estimate," "expect," "intend," "likely," "may," "might," "objective," "ongoing," "plan," "potential," "predict," "project," "should," "to be," "will," "would," or the negative or plural of these words, or similar expressions or variations, although not all forward-looking statements contain these words. We cannot assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur and actual results could differ materially from those expressed or implied by these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified herein, and those discussed in the section titled "Risk Factors" set forth in Part II, Item 1A. of the Company's Quarterly Report on Form 10-Q filed with SEC on November 3, 2025, and our other filings, each of which is on file with the Securities and Exchange Commission. These risks are not exhaustive. New risk factors emerge from time to time, and it is not possible for our management to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date hereof and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely upon these statements. Except as required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

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PYXIS ONCOLOGY, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	**2024**	**2025**	**2024**
Revenues				
Milestone revenue	$ —	$ —	$ 2,820	$ —
Royalty revenues	—	—	—	8,146
Sale of royalty rights	—	—	—	8,000
Total revenues	—	—	2,820	16,146
Costs and operating expenses				
Cost of revenues	—	—	—	475
Research and development	17,808	17,741	51,985	44,723
General and administrative	5,653	6,013	16,960	20,339
Total costs and operating expenses	23,461	23,754	68,945	65,537
Loss from operations	(23,461)	(23,754)	(66,125)	(49,391)
Other income, net:				
Interest and investment income	774	1,846	3,010	5,419
Sublease income	684	705	1,883	2,212
Total other income, net	1,458	2,551	4,893	7,631
Loss before income taxes	**(22,003)**	**(21,203)**	**(61,232)**	**(41,760)**
Income tax expense	—	—	283	—
Net loss	**$ (22,003)**	**$ (21,203)**	**$ (61,515)**	**$ (41,760)**
Net loss per common share - basic and diluted	$ (0.35)	$ (0.35)	$ (0.99)	$ (0.73)
Weighted average shares of common stock outstanding - basic and diluted	62,557,386	60,715,041	61,847,245	57,511,997

PYXIS ONCOLOGY, INC.

Condensed Consolidated Balance Sheets
(In thousands, Unaudited)

	September 30, 2025	**December 31, 2024**
Assets		
Current assets:		
Cash and cash equivalents	$ 8,919	$ 19,473
Marketable debt securities, short-term	67,337	107,458
Restricted cash	1,472	1,472
Prepaid expenses and other current assets	5,345	4,037
Total current assets	83,073	132,440
Property and equipment, net	8,460	9,899
Intangible assets, net	2,434	2,600
Operating lease right-of-use asset	11,637	12,242
Total assets	**$ 105,604**	**$ 157,181**
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 9,756	$ 4,859
Accrued expenses and other current liabilities	7,996	11,371
Operating lease liabilities, current portion	1,630	1,450
Total current liabilities	19,382	17,680
Operating lease liabilities, net of current portion	17,400	18,650
Financing lease liabilities, net of current portion	43	100
Total liabilities	36,825	36,430
Commitments and contingencies		
Stockholders' equity:		

Preferred stock	—	—
Common stock	62	60
Additional paid-in capital	493,719	484,077
Accumulated other comprehensive income	69	170
Accumulated deficit	(425,071)	(363,556)
Total stockholders' equity	68,779	120,751
Total liabilities and stockholders' equity	**$ 105,604**	**$ 157,181**